

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE LITIGATION**

)
) **MDL No. 1456**
) **Master File No. 01-CV-12257-PBS**
) **Subcategory Case. No. 06-11337**
)

THIS DOCUMENT RELATES TO:

*United States of America ex rel. Ven-A-Care of the
Florida Keys, Inc., et al. v. Dey, Inc., et al.,*
Civil Action No. 05-11084-PBS

) **Hon. Patti B. Saris**
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**DEY DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT
OF THEIR MOTION *IN LIMINE* TO EXCLUDE FROM EVIDENCE
THE REPORTS AND TESTIMONY OF THEODORE R. MARMOR, PH.D.**

Defendants Dey Pharma, L.P. (formerly known as Dey, L.P.), Dey, Inc., and Dey L.P., Inc. (collectively "Dey") submit this memorandum of law in support of their Motion to Exclude From Evidence the Reports and Testimony of Theodore R. Marmor, Ph.D. ("Dr. Marmor").¹

PRELIMINARY STATEMENT

Plaintiffs intend to introduce at trial the testimony of Dr. Marmor as a purported "rebuttal" expert witness. Dr. Marmor, however, does not seek to rebut any other expert testimony. Rather, Dr. Marmor's testimony is designed to rebut decades of knowledge by the United States that AWP was nothing more than a benchmark price that did not – and was well-known to not – represent an actual average of wholesale prices. Specifically, Dr. Marmor would testify that, despite having knowledge that AWP was not an actual transaction price, the government's continued reliance on it as a basis for reimbursement cannot be viewed as an

¹ Dr. Marmor's reports and relevant deposition testimony are attached, along with all other exhibits referenced herein, to the Declaration of Neil Merkl in Support of Dey Defendants' Motion *In Limine* to Exclude from Evidence the Reports and Testimony of Theodore R. Marmor, Ph.D., sworn to on March 12, 2010 ("Merkl Decl.").

indication that the government “approved” of or had “acquiesced” to industry-standard norms regarding AWP reporting. Dr. Marmor’s testimony is not admissible as expert testimony under Rule 702 of the Federal Rules of Evidence because it is neither relevant nor reliable.

As the Court previously observed, Dr. Marmor’s opinions mostly consist of general observations on health care policy, his understanding of Medicare and Medicaid history, and how bureaucracy purportedly works. Merkl Decl. Ex. 1, Transcript of Motion for Certification of Appealability, July 24, 2008, at 18:1-19:15. While Dr. Marmor intends to give testimony concerning approval and acquiescence, he brings no specialized knowledge to this task, and his deposition testimony reveals that he would do no more than instruct the jury on these issues based on the dictionary definitions of the words. Moreover, faced with a record replete with evidence of the government’s knowledge concerning AWP and its continued reliance on AWP in spite of that knowledge, all Dr. Marmor can say is that there was no approval or acquiescence because his limited review of certain evidence spoon-fed to him by Plaintiffs did not reveal a document specifically and explicitly approving AWP reporting. Surely, this is a concept the jury can understand without Dr. Marmor’s testimony. Dr. Marmor’s testimony, therefore, is irrelevant and will not assist the trier of fact.

Moreover, Dr. Marmor’s testimony is not based on sufficient facts, his testimony is not the product of reliable methods, and he has failed to apply his methods reliably to the facts of the case, all of which also call for the exclusion of Dr. Marmor’s opinions.

SUMMARY OF DR. MARMOR’S TESTIMONY

Dr. Marmor is a so-called rebuttal witness for Plaintiffs, brought in to challenge the defense that the government knew AWP was a benchmark price and that its continued use in drug reimbursement constituted approval of or at least acquiescence in Defendants’ reporting of

AWPs. Merkl Decl. Ex. 2, Deposition of Dr. Marmor, February 11, 2009, at 40:5-44:1.

Plaintiffs' Rule 26(a)(2)(B) disclosures in this case concerning Dr. Marmor consist of his expert report prepared for Plaintiffs' case against Abbott Laboratories, Inc. and a four page "supplemental" report concerning Dey and Roxane. *See* Merkl Decl. Ex. 3, Expert Report of Professor Theodore R. Marmor, Ph.D., and Ex. 4 Supplemental Expert Report of Professor Theodore R. Marmor, Ph.D. Dr. Marmor's report concerning Abbott Laboratories consists largely of a 34-page recitation of the history of drug reimbursement policies under the Medicaid and Medicare programs², followed by four pages of perfunctory analysis in which Dr. Marmor concludes "that neither the federal nor state governments approved of--or even acquiesced in--Abbott's price reporting conduct as alleged in this case." Merkl Decl. Ex. 3 at ¶ 85. In his supplemental report, Dr. Marmor simply rehashes the main "conclusions" in his Abbott report, and summarily concludes that his opinions are "equally relevant to the Dey and Roxane cases." *Id.* at ¶ 8. En route to his conclusions, Dr. Marmor dismisses the idea that if the government knew about the pricing practices of the pharmaceutical industry, "then its 'failure' to change the AWP and related policies constituted governmental acquiescence--or even an embrace of these pricing practices." Merkl Decl. Ex. 3 at ¶ 20.

Despite the government's knowledge and inaction, Dr. Marmor concludes there was no approval or acquiescence simply because he saw no single document specifically saying so. In

² The record in this action consists of documents produced by CMS that were created at or around the same time many of the policy changes Dr. Marmor discusses were implemented, as well as hundreds of hours of deposition testimony from current and former CMS officials and state Medicaid officials who would have direct knowledge of their implementation. Yet, in his recitation of the history of Medicaid and Medicare drug reimbursement policies, Dr. Marmor makes minimal references to evidence in the record and instead relies on a handful of publicly available documents and secondary source material, such as news media articles and other publications, many of which he authored or co-authored. The few references to the record he does make consist mainly of documents produced by Abbott Laboratories purportedly concerning its lobbying efforts, which are irrelevant to Plaintiffs' claims against Dey.

forming his opinions, Dr. Marmor – not in any way based on the actual legal standards applicable here – took the ordinary dictionary definitions of approval and acquiescence and fashioned tests for what the government would need to say and do. Merkl Decl. Ex. 2 at 165:16-191:8. Basically, his tests state: “Acquiescence is to accept as okay. Approval is to say it is positive.” *Id.* at 191:6-8. Applying these simple definitions, Dr. Marmor would require the government to make some sort of “authoritative statement” or “explicit acknowledgement” to satisfy his tests. *Id.* at 45:13-46:11; 165:16-166:20.

In order to give his opinions a veneer of expert analysis, Dr. Marmor tries to connect his ad hoc “tests” to three models of analysis propounded by Professor Graham Allison in the 1971 book *Essence of Decision: Explaining the Cuban Missile Crisis*. Allison used these models to look at the Cuban Missile Crisis from three points of view: the unitary actor approach, the organizational process approach, and the bureaucratic/governmental politics approach. Merkl Decl. Ex. 3 at ¶¶ 14, 16, 18. Although Dr. Marmor’s opinions here are based on simple concepts and dictionary definitions, he attempts to shoehorn them into Professor Allison’s models. With these dubious methods, Dr. Marmor reviewed a narrow set of documents and testimony fed to him by the Plaintiffs. The result is a deeply flawed and unhelpful academic treatment of ordinary issues that should be left to the jury.

ARGUMENT

Rule 702 of the Federal Rules of Evidence only allows expert testimony “[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue.” It is fundamental that expert testimony assist the trier of fact: “testimony must be relevant not only in the sense that all evidence must be relevant ... but also in the incremental sense that the expert’s proposed opinion, if admitted, likely would assist the

trier of fact to understand or determine a fact in issue.” *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 80 (1st Cir. 1998) (citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 591-592 (1993)). Moreover, the purported expert opinions must be sufficiently reliable and will not be admitted unless: “(1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.” FED. R. EVID. 702. The trial court must determine whether the expert’s testimony “both rests on a reliable foundation and is relevant to the task at hand.” *Daubert*, 509 U.S. at 597. The court’s gatekeeping function extends to all expert testimony and “not merely to evidence involving scientific conclusions.” *Coastal Fuels of Puerto Rico, Inc. v. Caribbean Petroleum Corp.*, 175 F.3d 18, 34 (1st Cir. 1999); *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999).

I. DR. MARMOR’S TESTIMONY WILL NOT ASSIST THE TRIER OF FACT

Expert testimony that merely explains a matter within the common knowledge of lay persons cannot be admitted under Rule 702 because such testimony will not assist a jury. *See, e.g., United States v. Zajackauskas*, 441 F.3d 32, 39 (1st Cir. 2006) (“Expert testimony does not assist where the [trier of fact] has no need for an opinion because it easily can be derived from common sense, common experience, the [trier of fact’s] own perceptions, or simple logic.”); *Brown v. Wal-Mart Stores, Inc.*, 402 F. Supp. 2d 303, 309 (D. Me. 2005) (excluding expert testimony that “merely place[ed] an expert sheen on common sense”). In *Brown v. Wal-Mart Stores, Inc.*, for instance, the court excluded expert testimony concerning improper storage of merchandise that fell and injured a customer, deeming the expert’s conclusions “as old as humanity itself: (1) if something is bumped, objects may fall; and, (2) the more bumped, the more likely.” *Id.*

Dr. Marmor's opinions concern subject matter within the ken of ordinary jurors and are not, therefore, admissible as they will not assist the trier of fact. In his testimony, Dr. Marmor simply applies the ordinary dictionary definitions of approval and acquiescence to arrive at his conclusion. The jury can also read the dictionary—these are concepts they can understand. Dr. Marmor's testimony simply does not help.

A. The Testimony Lacks Specialized Knowledge And Is Irrelevant

Dr. Marmor's area of testimony is straightforward and would not assist the jury any more than a dictionary would. The crux of Dr. Marmor's "analysis" is based on simple concepts, understandable by any person of reasonable intelligence – namely whether conduct constitutes "approval" or "acquiescence." Despite his extensive references to Prof. Graham Allison's "models" of analysis and his overall professorial gloss, there is nothing about his analysis that is scientific, technical, or otherwise beyond the grasp of an ordinary juror.

In formulating his standard for government approval Dr. Marmor does not rely on any political science standard or methodology, but rather gives the word "approval" its ordinary meaning. Merkl Decl., Ex. 2 at 165:16-166:20, 171:22-172:7. In describing his definition of "approval," Dr. Marmor stated: "It needs to fill the ordinary definition or meaning of the word approval. This is okay. There are many, many synonyms of that expression including I approve of this." *Id.* at 171:22-172:7. Dr. Marmor admitted "I don't think the word approval has a political science stipulated definition that is used." *Id.* at 185:5-17.

Dr. Marmor's "acquiescence" standard is likewise derived from the ordinary, everyday meaning of the word, not some standard or methodology from the field of political science. Dr. Marmor described acquiescence as "a less vigorous form of the general category of approval or going along with something. It's acceptance of the status quo without, without the premise or

without the premise that it should be changed at least for now.” *Id.* at 190:6-13. This is not a political science standard, as Dr. Marmor himself conceded. *Id.* at 202:11-203:2.

The concepts of government approval and acquiescence – as articulated by Dr. Marmor – are straightforward and do not require any special expertise. Dr. Marmor says as much, despite his unnecessary academic spin. Nor do the application of these standards require any special expertise. A jury could just as easily apply these standards to the evidence as Dr. Marmor. Accordingly, his testimony is unnecessary.

B. Dr. Marmor Should Not Be Permitted To Recite The Record For The Jury

Dr. Marmor spends the bulk of his report, over thirty pages, lecturing on Medicare and Medicaid purposes, policies, and politics. Merkl Decl. Ex. 3 at ¶¶ 25-84. Dr. Marmor repeated much of the same history lesson at his deposition and would no doubt do so at trial. This sort of professorial recitation of the record is improper and will not assist the jury. Courts routinely exclude expert testimony that amounts to no more than a narrative of the record. *See, e.g., In re Rezulin Products Liab. Litig.*, 309 F. Supp. 2d 531, 551 (S.D.N.Y. 2004) (excluding expert testimony amounting to a “narrative of the case which a juror is equally capable of constructing”); *University of Pittsburgh v. Townsend*, No. 3-04- cv-291, 2007 WL 1002317, 17 (E.D. Tenn. 2007) (excluding expert testimony when expert merely “offered his interpretation of facts that are already in the record” and “essentially marshaled the facts in the record which support the [party’s] position.”).

For example, in *In re Rezulin Products Liab. Litig.*, Plaintiffs’ expert proposed to testify “to a narrative reciting selected regulatory events concerning Rezulin, including Advisory Committee meetings, labeling changes, “Dear Doctor” letters, and approval and withdrawal decisions by regulators in the United States and abroad.” 309 F. Supp. 2d at 551. The court concluded that “[s]uch material, to the extent it is admissible, is properly presented through

percipient witnesses and documentary evidence.” *Id.* The court further found “the glosses that Dr. Gale interpolates into his narrative are simple inferences drawn from uncomplicated facts that serve only to buttress plaintiffs’ theory of the case.” *Id.* The same is true here. The record narrative should be presented with relevant witnesses and documents, not by Dr. Marmor. Interpreting the record is the jury’s job. Dr. Marmor’s unhelpful testimony must be excluded.

II. DR. MARMOR’S TESTIMONY IS NOT BASED UPON SUFFICIENT FACTS

Dr. Marmor also failed to consider sufficient documents and other information to form reliable opinions. Under Rule 702, Dr. Marmor’s testimony must be based on sufficient facts. The court should exclude his testimony if it does not rest on a reliable foundation of pertinent evidence. *Daubert* at 597; *see also Damon v. Sun Co. Inc.*, 87 F.3d 1467, 1474 (1st Cir. 1996) (“[A]n expert should not be permitted to give an opinion that is based on ... an insufficient evidentiary foundation.”)(internal citation omitted)). Courts routinely exclude testimony where experts rely on insufficient information. *See, e.g., Irvine v. Murad Skin Research Labs.*, 194 F.3d 313, 321 (1st Cir. 1999)(vacating judgment for plaintiff in breach of contract suit where plaintiff’s damages expert’s conclusions were not supported by factual data).

A. Dr. Marmor Only Read What The Plaintiffs Gave Him To Read

Dr. Marmor failed to consider sufficient facts to form a reliable and admissible expert opinion because he principally relied on the documents the Plaintiffs gave him. Numerous courts have excluded or limited expert testimony because such selective methods are unreliable. *See, e.g., Roussell v. Brinker Int’l, Inc.*, 2008 U.S. Dist. LEXIS 52568, *107 (S.D. Tex. July 9, 2008) (finding that expert’s conclusions are less reliable when based on materials and individuals selected by counsel for review, expert did not know how the selections were made, and the small sample of data reviewed weighed against admissibility); *McGovern v. Brigham & Women’s Hosp.*, 584 F. Supp. 2d 418, 424 (D. Mass. 2008) (excluding testimony that was based on

research conducted only for litigation and testifying); *Lippe v. Bairnco Corp.*, 288 B.R. 678, 696-697 (S.D.N.Y. 2003) (excluding testimony because expert was unable to explain bases for opinion and relied on what counsel told her rather than conducting independent investigation). Rather than engage in his own independent investigation, Dr. Marmor allowed himself to be fed filtered information by the Plaintiffs. Not only was his review inadequate, but his testimony is infected with potential bias and must be excluded.

Dr. Marmor mainly considered reviewing what the Department of Justice sent to his office: select documents produced in this case and certain state Medicaid depositions. Merkl Decl. Ex. 2 at 15:21-17:21; Merkl Decl. Ex. 5, Marmor Abbott Report Source Log; Merkl Decl. Ex. 6, Marmor Supplemental Report Source Log; Merkl Decl. Ex. 7, Marmor Supplemental List of Materials Considered; Merkl Decl. Ex. 8, State Medicaid Deposition List. The Breen Law Firm also hand-picked documents for his review. Merkl Decl. Ex. 2 at 20:22-21:18; Merkl Decl. Ex. 9, Deposition of Dr. Marmor, February 12, 2009, at 446:8-447:17, 458:22-459:21. Of these documents, Dr. Marmor only actually read a smaller set gathered by his research assistants. Merkl Decl. Ex. 2 at 16:8-18. His review process consisted of:

Working with a team in New Haven and telling them what I was interested in and asking them to extract that from the rather large body of materials that was passed on to us in the course of preparing for this.

Id. For example, the Department of Justice provided Dr. Marmor with only 41 depositions of current and former state Medicaid officials, despite the fact that there have been well over 100 such depositions taken in these actions to date. *See* Merkl Decl. Ex. 8. Of those 41 State Medicaid depositions provided to him, Dr. Marmor only read parts of 6, and “thumbed through” some others. Merkl Decl. Ex. 2 at 19:2-20:14. Dr. Marmor’s “research” was really a narrow review of information that had already been cherry-picked for him by Plaintiffs’ counsel. Under

similar circumstances, the court excluded expert testimony in *Roussell v. Brinker Int'l, Inc.* because it was not based on a reliable methodology and was inconsistent with *Daubert*. 2008 U.S. Dist. LEXIS 52568 at *107. There, the expert reviewed 34 deposition transcripts and deposition summaries provided by defense counsel. *Id.* at *101. Of the deposition transcripts, the expert only read 11 completely. *Id.* The expert also interviewed employees hand-picked by counsel at restaurants chosen by counsel. *Id.* at 102. Plaintiffs' heavy hand in Dr. Marmor's review process is equally troubling and weighs against admissibility.

By and large, Dr. Marmor cannot recall what particular documents and depositions he actually read, saying only that he would recognize something he reviewed. Merkl Decl. Ex. 2 at 16:19-17:6. He attributes his uncertainty to the "huge amount of material that came through" from the Plaintiffs. *Id.* It is also unclear to what extent his conclusions are based on his own experience or on research for previous state AWP cases. *See* Merkl Decl. Ex. 10, Dr. Marmor Email Re: AWP Involvement Timeline (showing depositions in Alabama and Missouri). Without an identifiable and sufficient factual basis, Dr. Marmor's opinions are simply not reliable.

B. Dr. Marmor Could Not Review Deliberative Process Information

In forming his opinions, Dr. Marmor could not consider important documents and potential deposition testimony as result of the United States' assertion of the deliberative process privilege. The United States withheld numerous documents and blocked any testimony that touches on the deliberative process of the federal government. Such information, however, goes directly to the internal deliberations of the government over drug reimbursement policy and is critical to determining whether the government has approved or acquiesced. Dr. Marmor recognized the importance of deliberative process information in his own expert report:

To understand what stakeholders were doing over time one has to investigate what they said, what they claimed, what they thought they knew, what confused them, and what options for action they in fact had.

Merkel Decl. Ex. 3 at ¶ 41. The United States has consistently shielded this information. For example, at the deposition of CMS official Larry Reed, defense counsel asked: “Did Medicaid ever consider using the actual acquisition cost by itself as a permissible means of reimbursement?” Merkel Decl. Ex. 11, Deposition of Larry Reed, October 2, 2008, at 1233:1-3. The United States objected and instructed Mr. Reed not to answer “on the grounds of deliberative process.” *Id.* at 1233:4-6. An answer to such a question would shed light on what the government actually knew about AWP and really thought in continuing its use in reimbursement policy. Having asserted these objections and blocked the discovery of this information, it cannot have it both ways. Without reviewing this kind of deliberative process information, Dr. Marmor cannot possibly give a reliable opinion on whether or not the federal government approved of or acquiesced in the Defendants’ alleged conduct.

III. THE TESTIMONY IS NOT THE PRODUCT OF RELIABLE METHODS

A. The Allison Models Are Inapplicable Here

Rule 702 requires that expert testimony be based on a reliable methodology. Any step that renders the methodology unreliable renders the expert’s testimony inadmissible. *United States v. Monteiro*, 407 F. Supp. 2d 351, 374 (D. Mass. 2006) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994)). “This is true whether the step completely changes a reliable methodology or merely misapplies that methodology.” *Id.* Simply put, it is “improper to testify on the basis of a methodology that is transposed from one area to a completely different area of inquiry—at least if there is no independent research supporting the transposition.”

Commentary to Rule 702, Stephen A. Saltzburg, Daniel J. Capra, and Michael M. Martin (citing *Braun v. Lorillard Inc.*, 84 F.3d 230 (7th Cir. 1996)).

Dr. Marmor's testimony must be excluded because the Allison models he purports to use cannot be transposed to fit this case. These "models" were set out in the 1971 book *Essence of Decision: Explaining the Cuban Missile Crisis*, by Graham Allison. The models break down three approaches to understanding the Cuban Missile Crisis – a two week event. Professor Allison used his models in an attempt to explain the Cuban Missile Crisis and how it evolved: why the Soviet Union placed missiles in Cuba, why the United States responded with a blockade, and why the Soviet Union ultimately withdrew the missiles.

In stark contrast to Professor Allison's use of his models of analysis, which he applied to an international event with a small number of actors and a duration of just two weeks, Dr. Marmor purports to use the models to decipher conduct occurring over the course of more than four decades and involving numerous actors, including nine presidents, fifty states, and thousands of government officials. Dr. Marmor's misuse of the Allison models by taking them so far outside the context they were designed for renders his opinions that flow from there unreliable and, therefore, inadmissible. Dr. Marmor himself recognized that Allison's "application of the models was to a sphere of public policy and to a set circumstances which were quite special." Merkl Decl. Ex. 12, Deposition of Dr. Marmor, February 13, 2009, at 832:8-833:18. Dr. Marmor conceded that the Allison models have a "very prominent role" in the literature of foreign policy, but he argues they also have a role in the literature of business management, including his "area of welfare state politics." *Id.* at 843:12-844:15. However, the models do not fit this case—the circumstances are dramatically different.

In particular, the long period of time at issue here makes applying the models difficult. According to Dr. Marmor, “the information costs of acquiring the kind of data that is required for a full Model III account is almost impossible require over thirty or forty years.” *Id.* at 837:3-840:2. Model III is geared towards brief historical events with a short window of information. As the duration of an event is extended, the difficulty of acquiring adequate historical information increases. *Id.* Model III is simply not designed for, or capable of, explaining over forty years of government conduct.

Furthermore, Dr. Marmor is apparently the only person who has ever used the models to analyze welfare state politics. General acceptance of the expert’s methods in his field is an important factor in evaluating reliability. *Daubert*, 509 U.S. at 593-594. But the closest case Dr. Marmor could think of was a study conducted by one of his former students concerning the “building of the dome stadium in Minneapolis over a fifteen-year period.” Merkl Decl. Ex. 12 at 832:8-833:18, 841:6-842:8. That analysis, about disputes over the location of the stadium and other concerns about that one project, is hardly comparable to the situation here. *Id.* at 844:17-845:9. Dr. Marmor claims the models are often used in his field, but he cannot name any other analyses explicitly applying them. *Id.* at 834:9-21, 844:10-12. There is no evidence that the models have been generally accepted in analyzing long-term domestic policy matters or that they can be successfully transposed for such purposes.

In any event, the Allison models are largely irrelevant to the central focus of Dr. Marmor’s analysis, and it appears they were included in his report solely to create the appearance that his opinions qualify as “expert opinions.” They do not. As discussed *supra* at Part I(A), the crux of Dr. Marmor’s opinions – whether the United States approved of or acquiesced in Dey’s conduct – does not rest on complicated standards requiring specialized expertise, but rather a

basic understanding of the everyday meaning of those words. Indeed, Dr. Marmor's testimony shows that all the necessary tools to understand government approval and acquiescence are in the dictionary. Ultimately, approval means "to say it is positive" and acquiescence means "to accept as okay." Merkl Decl. Ex. 2 at 190:21-191:8. The models only confuse the analysis. Dr. Marmor's application of the models on top of his ordinary definitions is improper and misleading, and the resulting conclusions are unreliable and must be excluded.

B. Dr. Marmor Developed His Opinions Solely for Litigation

Dr. Marmor's testimony is also unreliable because it is unrelated to his academic study and scholarship. Dr. Marmor formed his opinions purely for purposes of this litigation. In evaluating the reliability of expert testimony, an important question is whether the expert is "proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *McGovern v. Brigham & Women's Hosp.*, 584 F. Supp. 2d 418, 423-424 (D. Mass. 2008)(quoting *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995)). Dr. Marmor's opinions on drug reimbursement policy do not flow from his previous work on Medicare and health care policy issues. He did not do any studies independent of the AWP litigation. Rather, Dr. Marmor developed his opinions at the urging of Plaintiffs' counsel.

Although Dr. Marmor has researched, written, and taught a great deal on the subject of health care policy in general, he never specifically studied drug reimbursement policy, and except for the work he was asked to perform by Plaintiffs' counsel for purposes of this litigation, he still hasn't. Merkl Decl. Ex. 9, Deposition of Dr. Marmor, February 12, 2009, at 459:22-462:9. In his hundreds of published works, Dr. Marmor never once opined on the issues in this case, which was only brought to his attention in September 2004, when the Connecticut Attorney General's office contacted him about the "possibility of being called as expert in awp case."

Merk1 Decl. Ex. 10. It was not until 2006 that Dr. Marmor started “serious research” for the first time, at the direction of Alabama, Missouri, and the United States Department of Justice. Merk1 Decl. Ex. 9 at 432:11-20. Critically, Dr. Marmor admits he was not an expert on drug reimbursement policy before joining the AWP litigation. *Id.* at 461:5-14. Now he claims that status, based on his work at the behest of Plaintiffs’ counsel, performed solely for purposes of litigation. These facts further undermine the reliability of his testimony.

IV. DR. MARMOR’S CONCLUSIONS CANNOT BE VERIFIED

Assuming the Allison models had some applicability to the issues in this action – which they do not – Dr. Marmor nevertheless fails to apply them reliably or in a manner that permits his conclusions to be verified. Instead, Dr. Marmor’s testimony mainly consists of conclusory statements and unsupported, subjective opinions. The failure to apply a methodology undermines the reliability of Marmor’s testimony because there is no way to verify his conclusions. *See, e.g., Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 80-81 (1st Cir. 1998) (holding that assessment of reliability includes consideration of the “verifiability of the expert’s theory or technique”). Dr. Marmor did not explain his analytical process in any traceable detail, and, therefore, his alleged application of the Allison models cannot be tested or replicated. As a result, his opinions are just conclusory statements without a reliable foundation. Such statements are subjective and inadmissible. *Daubert*, 509 U.S. at 590.

Numerous courts have excluded testimony that is not supported by any methodology but instead is comprised of conclusory statements. *See, e.g., Nna v. Am. Std., Inc.*, 630 F. Supp. 2d 115, 137 (D. Mass 2009) (excluding portions of testimony based on expert’s general impression “[i]n the absence of any identifiable methodology”); *Scrofani v. Stihl, Inc.*, 44 Fed. Appx. 559, 562 (3d Cir. 2002) (testimony inadmissible where expert employed no methodology, merely setting forth “a series of unsubstantiated opinions”); *Smith v. Freightliner, LLC*, 239 F.R.D. 390,

392-93 (D.N.J. 2006) (holding that expert's methodology could not be replicated and conclusion could have been pulled "out of a hat").

In his expert report, after explaining the models at the outset, Dr. Marmor fails to then explain how they inform his opinions and conclusions. Dr. Marmor hardly mentions the models at all in most of his report, instead offering a series of unsubstantiated subjective opinions. This sort of speculation was excluded in *Nna v. Am. Std., Inc.*, where the expert failed to apply any methodology in jumping to the conclusion that railroad employees had enough time to get out of the way of an oncoming train. 630 F. Supp. 2d at 136-137. The court found the expert's useless opinion was based on nothing more than his "general impression of how quickly experienced railroad employees can move." *Id.* at 136.

On the rare occasion when Dr. Marmor does mention the models in his "analysis," he speaks of them only in conclusory terms and fails to substantiate how they inform or support his conclusions in a meaningful or verifiable way. For example, in one of the few instances where Dr. Marmor actually attempts to draw a link between one of Allison's Model's and the conclusion in his report, he simply states:

More direct, particular evidence of formal authoritative approval would be required, according to the organizational process model [i.e., Allison's Model II], to establish governmental acquiescence in the type of drug price reporting conduct alleged in this case. Nothing I have seen indicates that federal or state policymaking organizations did so.

Merkel Decl. Ex. 3 at ¶ 22. However, Dr. Marmor offers no explanation as to how the application of Model II to the facts here leads to his conclusion, making it impossible to verify this claim. This sort of ipse dixit reasoning pervades Dr. Marmor's opinions and renders them unverifiable and, therefore, inadmissible.

Moreover, it appears from his deposition testimony that Dr. Marmor does not apply the Allison models in any systematic manner, but rather uses them as interpretive “lenses” without any real structure or steps. Merkl Decl. Ex. 2 at 178:22-180:7. These lenses give him “three different portraits” of the facts, from which he draws one subjective opinion. *Id.* For example, in concluding that there was not acquiescence, Dr. Marmor stated he was relying “on the standards of Model III to provide a description of the setting of the persons whose conduct was allegedly acquiescing in order to provide the premises for judging whether or not they were acquiescing when they were in a situation where non-action took place.” *Id.* at 203:3-204:2. This interpretive process is indecipherable and cannot be verified. Because Dr. Marmor applies the models so ambiguously, his resulting conclusory and subjective opinions are totally unreliable and must be excluded.

CONCLUSION

For all of the foregoing reasons, Dey respectfully requests that the Court grant Dey's motion to exclude the testimony of Dr. Marmor at trial, and to preclude the Plaintiffs from otherwise making use of, or relying upon, Dr. Marmor's opinions or testimony.

Dated: March 12, 2010

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on March 12, 2010, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Neil Merkl

Neil Merkl